

## REMARKS

The Office action mailed 8 February 2007, has been received and its contents carefully noted. The pending claims, claims 4, 11, 12, 22-25, 29, 30 and 32-34, were rejected. By this amendment, claim 1 has been amended, claims 33 and 34 have been canceled, and claims 35-40 have been added. Support may be found in the specification and the claims as originally filed. Specific support may be found in Examples 2-4 of the specification. No statutory new matter has been added. Therefore, reconsideration and entry of the claims as amended are respectfully requested.

### **Rejection under 35 U.S.C. 112, first paragraph**

The Examiner rejected the claims under 35 U.S.C. 112, first paragraph, as lacking written description. Specifically, the Examiner deemed that the lack of any false positive hypersensitivity reaction was not supported in the specification.

Applicants respectfully submit that the claims, as amended, do not refer to transient urticaria or false positive reactions of type I hypersensitivity. Thus, the amended claims comply with the written description requirement.

Therefore, the rejection under 35 U.S.C. 112, first paragraph, should properly be withdrawn.

### **Rejections under 35 U.S.C. 102(b) and 103(a)**

The Examiner rejected claims 4, 30, 32, 33 and 34 under 35 U.S.C. 102(b) as being anticipated by DOD-8B or Stitler et al. (1994 and 1995). The Examiner also rejected claims 4, 30, 32, 33 and 34 under 35 U.S.C. 102(b) as being anticipated by Stitler et al. (1998). The Examiner rejected claims 11, 21 and 22-25 under 35 U.S.C. 103(a) as being unpatentable over DOB-8B or Stitler et al. (1994 and 1995) or Stitler et al. (1998) in view of Reed et al.

Applicants respectfully submit that the claims, as amended, are directed to compositions *consisting of* a microfluidized slurry of at least one *Leishmania* parasite strain; TWEEN-80; glycerol; phenol; and saline. No where do the cited references, alone or in combination, teach or suggest a composition *consisting of* a microfluidized slurry of at least one *Leishmania* parasite strain; TWEEN-80; glycerol; phenol; and saline. No where do the cited references, alone or in

combination, teach or suggest a composition with the specific amounts and concentrations set forth in claims 35-40, i.e.  $0.35 \pm 0.05$  mg/ml of a microfluidized slurry of at least one *Leishmania* parasite strain; 0.001% TWEEN-80; 1% glycerol; and 0.4% phenol.

Since the cited art, alone or in combination, do not teach or suggest a composition *consisting of* a microfluidized slurry of at least one *Leishmania* parasite strain; TWEEN-80; glycerol; phenol; and saline in any amount or concentration, the claimed invention is novel and unobvious.

Therefore, the rejections under 35 U.S.C. 102(b) and 103(a) should properly be withdrawn.

#### **Request for Interview**

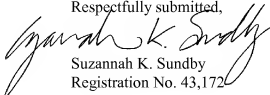
Applicants respectfully request either a telephonic or an in-person interview should there be any remaining issues.

### CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, in the event that additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. §1.136(a), and any fees required therefor are hereby authorized to be charged to **Deposit Account No. 210-380**, Attorney Docket No. **034047.013 (WRAIR 98-40/98-46)**.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Suzannah K. Sundby".

Suzannah K. Sundby  
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